REMARKS

Claims 23-35, 38, 41-47, and 49-79 are pending. Claims 23 and 60 have been amended. No new matter has been added by virtue of the amendment, support being found throughout the specification as filed.

The Examiner has objected to the drawings under 37 CFR 1.83(a). The Examiner indicates that the second angle of the cannula with respect to the piercing member must be shown or the feature canceled from the claims. Applicants have submitted corrected drawings under separate cover. Applicants note that original FIG. 3 corresponds now with FIG. 3A, original FIG. 4 corresponds now with FIG. 3B, and FIGS. 4A and 4B are new figures. Applicants point out support in the specification for the second angle of the cannula with respect to the piercing member at, for example, paragraphs [0023] and [0082] of the published application.

Claim Rejections- 35 U.S.C. § 102(b)

Claims 23, 24, 27 – 31, 38, 49, 51, 52, 54, 60, 61, 63, 64, 65, 67, and 79 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Palasis et al. (US Patent 6,969,371). Applicants respectfully traverse the rejection.

Independent claim 23, as amended, recites a method for treating an eye comprising inserting into an eye a device comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween along a longitudinal axis of the piercing member, and a cannula slidably disposed within the lumen, wherein the step of inserting the device into the eye comprises penetrating the eye with the piercing member and advancing the piercing member through the eye transconjunctively, advancing the cannula through the piercing member lumen towards a treatment site, piercing the treatment site with the cannula, and treating the eye by administering and/or aspirating material subretinally through the cannula.

Independent claim 27, as amended, recites a method of treating an eye, comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, the piercing member having a proximal end and a distal end and a lumen

defined therebetween, angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye, advancing a cannula through the piercing member lumen and beyond the distal end of the piercing member, guiding the cannula through the vitreous humor of the eye to the treatment site, and then treating the treatment site, thereby treating the eye.

Independent claim 60, as amended, recites a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member along a longitudinal axis of the outer member, and a piercing member at the distal end of the outer member, wherein the step of inserting the device into the eye comprises piercing the eye with the piercing member and advancing the piercing member and at least a portion of the outer member into the eye transconjunctively, advancing the cannula through the outer member and beyond the distal end to the treatment site, and administering and/or aspirating material through the cannula, thereby treating the eye.

With respect to independent claim 23 and 60, it is respectfully submitted that Palasis at least does not teach or suggest a method for treating an eye comprising inserting into an eye a device comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween along a longitudinal axis of the piercing member, and a cannula slidably disposed within the lumen (claim 23) or a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end and a cannula slidably disposed within the outer member along a longitudinal axis of the outer member (claim 60). Palasis further does not teach or suggest advancing the piercing member through the eye transconjunctively and advancing the cannula through the piercing member lumen as further set out in claim 23, or advancing the piercing member and at least a portion of the outer member into the eye transconjunctively and advancing the cannula through the outer member and beyond the distal end to the treatment site as further set out in claim 60.

Palasis describes a device that includes a primary penetrating member 24 and a secondary penetrating member 26. More specifically, the '371 reference is drawn to:

> A catheter comprising: a shaft having a proximal end and a distal end and a wall defining at least one aperture, the distal end of the shaft including a primary penetrating member ... wherein **the primary penetrating member is adapted to penetrate tissue in a first direction,** and wherein the **at least one secondary penetrating member** is retractable to a position within the primary penetrating member and **penetrates the tissue in a second direction different from the first direction** when extended from the primary penetrating member, **the shaft further comprising an insert having a lumen extending in a longitudinal direction of the shaft and transitioning to a generally lateral direction** adjacent the at least one aperture to direct the at least one secondary member through the at least one aperture. (claim 1; emphasis added).

Palasis, thus, stresses that the penetrating members penetrate the cardiac tissues in different directions because "by penetrating the tissue in a different direction, fluid leakage from the injection site is reduced." Thus, according to Palasis:

> The **secondary penetrating members 26 extend through apertures 34** defined through the wall of the primary penetrating member 24. The **apertures 34 each have an axis that is at an angle with the longitudinal axis of the primary penetrating member 24**. (col. 4, lines 63-67)

Thus, Palasis does not teach or suggest a method for treating an eye comprising inserting into an eye a device comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween along the longitudinal axis of the piercing member, and a cannula slidably disposed within the lumen, wherein the piercing member is advanced through the eye transconjunctively and the cannula is advanced through the piercing member lumen (i.e. along the longitudinal axis of the piercing member)(claim 23). Palasis likewise does not teach or suggest a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end and a cannula slidably disposed within the outer member along the longitudinal axis of the outer member, wherein the piercing member is advanced through the eye transconjunctively and the cannula is advanced through the piercing member lumen (i.e. along the longitudinal axis of the outer member)(claim 60).

With respect to independent claim 27, Applicants respectfully submit that Palasis at least does not teach a method of treating an eye comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye and angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye.

Further, with respect to the Office's assertion that Palasis "discloses using the specific device in the eye, and therefore fulfills the independent claims language on the basis of inherency (Office Action, p.5)", Applicants respectfully traverse.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . ; *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that **the missing descriptive matter is necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The **mere fact that a certain thing may result from a given set of circumstances is not sufficient**.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Thus, Applicants respectfully submit that Applicants' claim language is not fulfilled on the basis of inherency. Palasis specifically describes secondary penetrating members 26 that extend through apertures 34 defined through the wall of the primary penetrating member 24 such that the apertures 34 each have an axis that is at an angle with the longitudinal axis of the primary penetrating member 24. Further, a method of treating an eye, comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye and angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye is not necessarily present in the Palasis reference.

Further, the device and method of Palasis could not be modified so as to provide Applicants device and method because such a modification would render Palasis "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [Palasis]

was designed to operate" (see MPEP 2143.01). In particular, Palasis provides a device and method wherein fluid can be injected into tissue to reduce fluid leakage from the site by penetrating the tissue in a different direction. Modification of Palasis device and method would render Palasis unsuitable for this purpose.

Accordingly, independent claims 23, 27 and 60 are patentable over Palasis. Claims 24-26, 28-35, 38, 41-47, 49-59, and 61-79 depend from these claims and as such are patentable over paques. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections- 35 U.S.C. § 102(e)

Claims 23, 26, 27, 35, 38, 45, 47, 49, 50, 51, 56, 58, 59, 60 – 63, 70 – 79 have been rejected under 35 U.S.C. § 102(e) as being anticipated by LoRusso (US 2002/133184; the '184 reference). Applicants respectfully traverse the rejection.

Independent Claims 23 and 60

In particular, with respect to independent claim 23, LoRusso at least fails to teach or suggest a method for treating an eye comprising inserting into an eye a device comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween, and a cannula slidably disposed within the lumen, wherein the step of inserting the device into the eye comprises penetrating the eye with the piercing member and advancing the piercing member through the eye transconjunctively.

Similarly, with respect to independent claim 60, LoRusso at least fails to teach or suggest a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member, wherein the step of inserting the device into the eye comprises piercing the eye with the piercing member and advancing the piercing member and at least a portion of the outer member into the eye transconjunctively.

LoRusso describes a device and method for performing transscleral cautery and

subretinal drainage. The device includes a cautery section 210 adapted to cauterize tissue or other material that it contacts [0040] and an inner needle section 314 for providing subretinal drainage [0060]. As shown in Figs. 4A and 4B (reproduced, in part, below) and as described at [0056]-[0060], the device is inserted into the eye and is passed through the following layers: sclera 304, choroid 306, retinal pigment epithelium (RPE) 308, and subretinal space 310. In particular, the device penetrates the sclera 304 and the choroid 306 with the cautery section 210 being positioned in contact with the choroid 306 [0056], Fig. 4A. With the device positioned as such, transscleral cautery can be performed by heating the cautery section 210 [0057]. Subretinal drainage can then be performed by allowing the inner needle section 314 to penetrate through the RPE 308 and into the subretinal space 310, as shown in Fig. 4B, such that subretinal fluid can pass into the inner needle section 214 [0060].

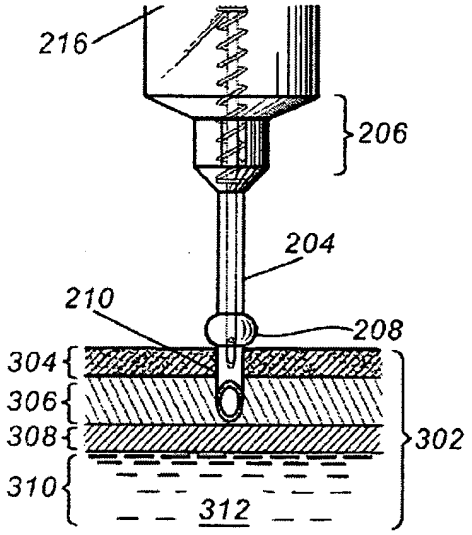

Fig. 4A

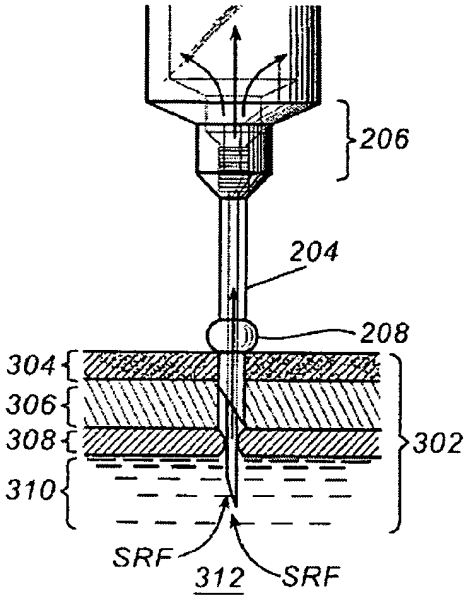

Fig. 4B

Thus, LoRusso clearly does not teach or suggest a method wherein the device is advanced into the eye transconjunctively (through the conjunctiva).

Applicants further note that LoRusso further fails to teach or suggest a method of

treatment. In particular, LoRusso provides no teaching or suggestion of use of the method for *administration* of material subretinally using the device of the invention. Rather, and as pointed out by the Examiner, LoRusso describes a method of performing surgery and subretinal drainage. LoRusso merely describes device useful for cautery and drainage procedures, but provides no teaching or suggestion that the apparatus as described can be used to deliver a therapeutic agent to subretinal tissue.

Thus, it is respectfully submitted that claims 23 and 60 are patentable over LoRusso. Claims 24-26, 38, 41-47, 74, 77, 78, 61-73, 76, 77, and 78 depend from claims 23 and 60 and, likewise, are patentable over LoRusso. Reconsideration and withdrawal of the rejection is respectfully requested.

Independent Claim 27

With respect to independent claim 27, Applicants respectfully submit that LoRusso at least does not teach or suggest a method of treating an eye comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye, and guiding the cannula through the vitreous humor of the eye to the treatment site.

LoRusso describes an approach wherein the cautery section 210 is advanced inferior to the supraorbital ridge, superior to the eye, and in a caudal direction so as to dispose the cautery section 210 within the choroid 306 (where it cauterizes the choroid) and so as to further advance the needle section 214 through the choroid 306, through the RPE 308, and into the subretinal space 310.

LoRusso does not teach or suggest inserting the device into the eye by piercing the eye with the cautery section 210 and advancing the cautery section 210 into the eye transconjunctively as shown in Applicants' Figures 3A-4B, into the vitreous humor of the eye, and guiding the cannula through the vitreous humor of the eye to the treatment site. This approach would result in LoRusso's device passing through the conjunctiva, through the vireous body, **followed by the macula, the retina, the choroid, and then the sclera**. This is contrary to

LoRusso's described method of passing the device **through the sclera, through the choroid, and into the retina** (through the RPE and into the subretinal space).

Further, the device and method of LoRusso could not be modified so as to provide the type of insertion and approach as taught by Applicants because such a modification would render the device of LoRusso "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [LoRusso] was designed to operate" (see MPEP 2143.01). In particular, LoRusso provides a device and method for performing transscleral cautery and subretinal drainage. If LoRusso's device was inserted as shown in Applicants' Figures 3A-4B, the cautery section 210 would not reach or enter the choroid and, thus, could not cauterize the choroid. Further, even if the cautery section 210 of LoRusso's device could somehow reach the choroid using Applicants' approach, subsequent subretinal drainage by allowing the inner needle section 314 to penetrate through the RPE 308 and into the subretinal space 310, as shown in Fig. 4B of LoRusso would not be possible because the cautery section 210, using Applicants' approach would be positioned beyond the retina. Further advancement of the inner needle section 314 would pass the inner needle section through the sclera and out of the back of the eye.

Thus, the device and method of LoRusso does not at all provide for entry of the device into the vitreous humor of the eye. Rather, according to LoRusso, the device only extends into the subretinal space.

Still further, LoRusso does not teach or suggest a method wherein, after the cautery section 210 is inserted into the eye and into the vitreous humor, the cautery section 210 is angled in any direction so as to guide the needle section 214 to any treatment site within the eye. This teaching comes purely from the present application.

Still further, LoRusso does not teach or suggest guiding the needle section 214 through the vitreous humor of the eye to the treatment site. According to LoRusso, the needle section 214 passes through the sclera 304, through the choroid 306, through the RPE 308, and into the subretinal space 312. The needle section 214 never enters the vitreous humor.

Applicants further note that LoRusso further fails to teach or suggest a method of treatment. In particular, LoRusso provides no teaching or suggestion of use of the method for *administration* of material subretinally using the device of the invention. Rather, and as pointed out by the Examiner, LoRusso describes a method of performing surgery and subretinal drainage. LoRusso merely describes device useful for cautery and drainage procedures, but provides no teaching or suggestion that the apparatus as described can be used to deliver a therapeutic agent to subretinal tissue.

Accordingly, it is respectfully submitted that claim 27 is patentable over LoRusso. Claims 28-35, 49-59, 75 and 79 depend from claim 27 and, likewise, are patentable over LoRusso. Reconsideration and withdrawal of the rejections is respectfully requested.

Claim Rejections- 35 U.S.C. § 103(a)

Claims 25, 32- 34, 41, 48, 53, 55, 57, 62, 66, 68 – 78, and 79 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Palais et al. reference (the '371 reference) and further in view of Paques et al (US Pub 2003/0171722; the '722 publication) and in view of Bowman et al (US Patent 6,378,526; the '526 reference). Applicants respectfully traverse the rejection.

Palasis, as discussed above, does not teach the elements of the claimed invention. Moreover, the combination of the Paques publication and Bowman do not cure the flaws of Palasis.

As set forth above, Palasis at least does not teach or suggest a method for treating an eye comprising inserting into an eye a device comprising a piercing member having a proximal end and a distal end and a lumen defined therebetween along the longitudinal axis of the piercing member, and a cannula slidably disposed within the lumen, wherein the piercing member is advanced through the eye transconjunctively and the cannula is advanced through the piercing member lumen (i.e. along the longitudinal axis of the piercing member)(claim 23). Palasis likewise does not teach or suggest a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end and a cannula

slidably disposed within the outer member along the longitudinal axis of the outer member, wherein the piercing member is advanced through the eye transconjunctively and the cannula is advanced through the piercing member lumen (i.e. along the longitudinal axis of the outer member)(claim 60). Further, Palasis at least does not teach a method of treating an eye comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye and angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye (claim 27).

There is no teaching or suggestion to modify Palasis in view of Paques to cure the above-noted deficiencies. In particular, Paques is designed for a specific purpose and, thus, modification would render Paques "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [Paques] was designed to operate" (see MPEP 2143.01).

Bowman et al. also does not remedy the above-noted deficiencies. Bowman et al. is cited for the delivery of steroids, genetic material, or pharmaceuticals to the eye. However, Bowman et al. does not teach or suggest the device or method set forth in claims 23, 27 and 60.

Accordingly, independent claims 23, 27 and 60 are patentable over Palasis, Paques, and Bowman. Claims 24-26, 28-35, 38, 41-47, 49-59, and 61-79 depend from these claims and as such are patentable over Palasis, Paques, and Bowman. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants believe that additional fees are not required in connection with the consideration of the within matter. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105.**

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

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